Remarks

The Office Action of June 14, 2010 has been received and reviewed. In this response, claims 1 and 20 have been amended and no claims have been cancelled or added. Upon entry of these amendments, claims 1, 3-6, and 8-34 will be pending in this application. Reconsideration and withdrawal of the rejections are respectfully requested as discussed herein.

Claim Amendments

Claims 1 and 20 have been amended to recite an elongate cable conductor comprising a plurality of wire strands forming a multilayered, conductive bundle that comprises an outer layer comprising multiple wire strands located around an inner layer that comprises multiple wire strands. Support for these amendments may be found in the application as filed at, e.g., paragraphs [0021] & [0029] and figures 4 & 6B.

The 35 U.S.C. §112, First Paragraph, Rejection

Claims 1, 3-6, and 8-34 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, it was asserted that the original specification lacks support for the "inter-twisted" wire strands within the cable conductor in combination with the other elements in the claim(s).

Although Applicants respectfully traverse this rejection and the assertions made in support of it, independent claims 1 and 20 have been amended to remove "inter-twisted" thereby rendering this rejection moot.

Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

The 35 U.S.C. §102 Rejection

Claims 1, 3-6, and 8-34 were rejected under 35 U.S.C. §102(b) as anticipated by Halperin et al. (U.S. Patent No. 5,564,434). Applicants respectfully traverse this rejection and the assertions made in support of it.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Applicants respectfully submit that Halperin et al. does not describe each and every element as set forth in claims 1, 3-6 and 8-34 and, as a result, a proper anticipation rejection has not been established with respect to claims 1, 3-6, and 8-34.

Among the reasons for Applicants' position that a proper anticipation rejection has not been established is that nothing has been identified within the disclosure of Halperin et al. that describes an elongate cable conductor comprising a plurality of wire strands forming a multilayered, conductive bundle that comprises an outer layer comprising multiple wire strands located around an inner layer that comprises multiple wire strands as recited in each of independent claims 1 and 20.

Although it has been asserted in the Office Action that the inner wire coiled lead conductor 16 of Halperin et al. is equivalent to the claimed elongate cable conductor, the inner wire coiled lead conductor 16 is not a multilayered, conductive bundle that comprises an outer layer comprising multiple wire strands located around an inner layer that comprises multiple wire strands, wherein the elongate cable conductor extends. Instead, the inner wire coiled lead conductor 16 is merely a plurality of wires wound in a single-layer coil. *See Halperin et al.*, column 7, lines 24-30.

In addition, Applicants also submit that a proper anticipation rejection has not been established because nothing has been identified within the disclosure of Halperin et al. that describes that an average gap exists between the insulative layer and an interior surface of the lumen of the coil conductor as recited in each of independent claims 1 and 20.

It has been asserted in the Office Action that "[s]ince the coil 14 and the coil 16 are formed from two separated components, there is necessarily a gap between the two, since they are not unitary." *Office Action*, June 14, 2010, page 5. First, claims 1 and 20 recite an average gap between the insulative layer and the interior surface of the lumen of the coil conductor—not between two coils as discussed in the Office Action.

Further, each of independent claims 1 and 20 recites that an average gap exists, and as a result, two components that are adjacent to each other, unless described otherwise, do not necessarily include an average gap simply because the two components are not unitary. (Please note: paragraph [0026] of the application as filed includes a discussion of an "average gap.")

If an average gap exists between the interior surface of the outer coiled wire lead conductor 16 and the inner insulating sheath 22 of Halperin et al. (located between coil 14 and coil 16), it does not appear to be described within the disclosure of Halperin et al. As a result, the Examiner appears to using an unexpressed teaching of Halperin et al. An unexpressed teaching is no more than an uncertain thing that may result from a given set of circumstances, and as a result, this rejection is essentially based on an inherent teaching of Halperin et al. (i.e., that an average gap exists between the interior surface of the outer coiled wire lead conductor 16 and the inner insulating sheath 22). The requirements for a rejection based on the doctrine of inherency, however, have not been met.

"The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. §2112(IV) (emphasis in original, citations omitted). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." M.P.E.P. §2112(IV), *citing In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999). "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." M.P.E.P. §2112(IV), *citing Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

For a proper anticipation rejection based on inherency, it must be shown, by fact or technical reasoning, that an average gap necessarily exists between the interior surface of the outer coiled wire lead conductor 16 and the inner insulating sheath 22. No such facts or reasoning have, however, been provided. Instead, only speculation has been offered to show that an average gap exists. Speculation alone is not, however, sufficient to support a *prima facie* obviousness rejection based on inherency, e.g., the mere fact that a certain thing may result from a given set of circumstances is not sufficient.

Still further among the reasons for Applicants' position that a proper anticipation rejection has not been established is that nothing has been identified within the disclosure of Halperin et al. that describes an electrically insulative layer formed as a coating on an exterior surface of the cable conductor, wherein the insulative layer has a relative dielectric coefficient less than approximately 10, as recited in each of independent claims 1 and 20.

Although it has been asserted in the Office Action that Halperin et al. discloses the use of polyurethane insulation, the polyurethane insulation of Halperin et al. is only described with reference to the polyurethane jacket/insulation covering 82, which is not shown or described as being formed as a coating on the exterior surface of the coil conductor 16 (which has been equated to the claimed cable conductor in the Office Action). Instead, the polyurethane jacket/insulation covering 82 extends only over the full length of the sensor module 20. *See Halperin et al.*, column 9, lines 59-67. Further, the insulating layer located between the inner coil 14 and the outer coil 16, in contrast, is described as a "tube." *See Halperin et al.*, column 9, lines 57-60.

Yet still further among the reasons for Applicants' position that a proper anticipation rejection has not been established is that nothing has been identified within the disclosure of Halperin et al. that describes an electrically insulative layer formed as a coating on an exterior surface of the cable conductor as recited in each of independent claims 1 and 20.

Although it has been asserted that "the examiner considers [the insulating sleeve 22] to be a coating over the cable conductor" (*Office Action*, June 14, 2010, page 4), Applicants disagree and reserve the right to argue this limitation in the future.

For at least these reasons, Applicants submit that the disclosure of Halperin et al. fails to describe each and every element as set forth in independent claims 1 and 20 (from which dependent claims 3-6, 8-19, and 21-34 depend). Applicants also submit that dependent claims 3-6, 8-19, and 21-34 recite features that further support patentability of those claims over Halperin et al.

For example, nothing has been identified within the disclosure of Halperin et al. as describing any of the elements of the dependent claims 3-6, 8-19, and 21-34. Instead, the elements set forth in these dependent claims appear to be discussed in the Office Action using obviousness concepts (*see Office Action*, June 14, 2010, pages 5-6), and as a result, an anticipation rejection cannot be supported.

For at least the reasons discussed above, Applicants submit that Halperin et al. does not anticipate claims 1, 3-6, and 8-34. Reconsideration and withdrawal of this anticipation rejection of claims 1, 3-6, and 8-34 are, therefore, respectfully requested.

The 35 U.S.C. §103 Rejection

Claims 1, 3-6, and 8-34 were rejected under 35 U.S.C. §103(a) as obvious over Halperin et al. (U.S. Patent No. 5,564,434) in view of Naylor et al. (U.S. Patent No. 5,491,299). Applicants respectfully traverse this rejection and the assertions made in support of it.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *See In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1970). Further, the Board of Patent Appeals and Interferences has confirmed that all claim limitations must be taught or suggest by the prior art to establish a case of *prima facie* obviousness as shown in the following except:

> When determining whether a claim is obvious, an examiner must make 'a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.' *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, 'obviousness requires a suggestion of all limitations in a claim.' *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (*citing In re Royka*, 490 F.2d 981, 985 (CCPA 1974)).
> *In re Wada*, Appeal 2007-3733, Application 10/613,220 (B.P.A.I. 2008).

Applicants respectfully submit that the combination of Halperin et al. in view of Naylor et al. does not teach or suggest all the elements recited in claims 1, 3-6, and 8-34 and, as a result, a *prima facie* case of obviousness has not been established with respect to claims 1, 3-6, and 8-34.

Although Halperin et al. has been provided in the Office Action to allegedly teach all the claim limitations in connection with the anticipation rejection, Naylor et al. has been provided in the alternative to replace the inner wire coiled lead conductor 16 of Halperin et al. with a cable conductor including inter-twisting conductors as allegedly described in column 5, lines 56-60.

Among the reasons for Applicants' position that a *prima facie* case of obviousness has not been established is that Naylor fails to teach or suggest an elongate cable conductor comprising a plurality of wire strands forming a multilayered, conductive bundle that comprises an outer layer comprising multiple wire strands located around an inner layer that comprises multiple wire strands as recited in each of independent claims 1 and 20.

Although it has been asserted in the Office Action that column 5, lines 56-60 of Naylor teaches an elongate cable conductor as claimed, the disclosure of Naylor et al. describes a multi-parameter cable 228 including a plurality of conductors in which each conductor is electrically shielded from each other. *See Naylor et al.*, column 5, lines 1-41. In other words, the plurality of conductors of the multi-parameter cable 228 is not a multilayered, conductive bundle that comprises an outer layer comprising multiple wire strands located around an inner layer that comprises multiple wire strands as recited in each of independent claims 1 and 20.

For at least these reasons, Applicants submit that a *prima facie* case of obviousness has not been established for independent claims 1 and 20 (from which dependent claims 3-6, 8-19, and 21-34 depend).

Further, Applicants submit that the proposed modification of the lead of Halperin et al. with the teachings of Naylor et al. would render it unsatisfactory for its intended purpose, and as a result, the combination of Halperin et al. and Naylor et al. cannot form a *prima facie* case of obviousness with respect to claims 1, 3-6, and 8-34.

> If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.
> M.P.E.P. § 2143.01(V) (*citing In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984)).

The inner coiled wire conductor 16 of Halperin et al. is coupled to an inner transition pin 58. More specifically, the proximal end of the inner transition pin 58 is slipped into the distal lumen of the inner coiled wire conductor 16 and the distal end of the inner coiled wire conductor 16 is crimped to the proximal end of the inner transition pin 58 by force applied to a crimp sleeve 66 slipped over the distal end of the inner coiled wire conductor 16. *See Halperin et al.*, column 8, line 66 to column 9, line 7. If the inner coiled wire conductor 16 of Halperin et al. were replaced with the multi-parameter cable 228, it would not define a lumen within which the inner transition pin 58 could be slipped into and such that a crimp sleeve 66 may apply force to the outside of the multi-parameter cable 228 to hold it on the inner transition pin 58. In other words, the multi-parameter cable 228 of Naylor et al. could not be coupled to the inner transition pin 58 as *intended* in Halperin et al.

Further, Halperin et al. further describes that the inner coiled wire conductor 16 defines a "stylet receiving lumen" (i.e., a lumen for receiving a stylet). *See Halperin et al.*, column 7, lines 28-30. As discussed herein, if the inner coiled wire conductor 16 of Halperin et al. were replaced with the multi-parameter cable 228, it would not define a lumen, and as a result, it would not include a stylet receiving lumen as *intended* in Halperin et al.

For at least these reasons, Applicants submit that the disclosure of Halperin et al. and Naylor et al. (taken alone or together) fails to provide a *prima facie* case of obviousness with respect to independent claims 1 and 20 (from which dependent claims 3-6, 8-19, and 21-34 depend). Applicants also submit that dependent claims 3-6, 8-19, and 21-34 recite features that further support patentability of those claims over Halperin et al. and Naylor et al.

For example, nothing has been identified in either of Halperin et al. and Naylor et al. (taken alone or together) that teaches or suggests the elements of dependent claims 3-6, 8-19, and 21-34. Instead, the following has been asserted:

> Halperin et al. discloses the claimed invention except for the specific ranges of the size of the coil, insulation and the gap dimensions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the size of the coil, insulation and the gap dimensions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05). Furthermore, determining the most appropriate size by routine experimentation would be prima facie obvious to one having ordinary skill in the art.
>
> Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the size and dimension of the lead components as taught by Halperin et al. with a specific range since it was known in the art that modifications to the size and dimension of lead components to create a larger or more compact lead, the would modify the lead to meet specific patient needs.
>
> As to claims 3, 8-14, 22-29, Halperin et al. discloses the claimed invention except for the preferred material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the the employed material as taught by Halperin et al. with the preferred material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 125 USPQ 416* (See MPEP 2144.07).

Office Action, June 14, 2010, pages 5-6.

Applicants respectfully traverse these assertions and submit that the obviousness doctrines regarding "optimum or workable ranges" and "preferred materials" do not replace the requirement that to establish a *prima* facie case of obviousness, all the claim limitations must be taught or suggested within the prior art. *See In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580

(CCPA 1970). *See also In re Wada*, Appeal 2007-3733, Application 10/613,220 (B.P.A.I. 2008). As noted previously herein, nothing has been specifically identified in Halperin et al. and Naylor et al. (taken alone or together) that teaches or suggests the elements of dependent claims 3-6, 8-19, and 21-34 as would be required for a *prima facie* case of obviousness.

For at least the reasons discussed above, Applicants submit that a *prima facie* case of obviousness has not been established for claims 1, 3-6, and 8-34 over Halperin et al. in view of Naylor et al. Reconsideration and withdrawal of this obviousness rejection of claims 1, 3-6, and 8-34 are, therefore, respectfully requested.

Summary

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

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